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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/746,635	11/13/96	MURTHY V	96700/341

HM22/1104

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EXAMINER	
GABEL,G	
ART UNIT	**PAPER NUMBER**
1641	27

DATE MAILED: 11/04/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/746,635	Murthy et al.
Examiner	**Group Art Unit**
Gailene R. Gabel	1641

☒ Responsive to communication(s) filed on *Oct 21, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *20* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 10/21/99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/746,635 is acceptable and a CPA has been established. An action on the CPA follows.

Amendment Entry

2. Applicants' amendment and response filed 7/12/99 in Paper No. 21 is acknowledged and has been entered. Claim 20 has been amended. Claims 21-23 have been canceled. Accordingly, claim 20 is pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In this case, the specification does not appear to provide any **literal support** for the recitation of "at least 20 U/L". Applicants point to Table 1 for support which discloses a number of specific adenylate kinase activities but fails to provide literal support for such recitation. Applicants also point to Figure 3 for support wherein the figure shows "20 U/L" on the vertical axis of the graph although Figure 3 also fails to provide literal support for such recitation. Furthermore, none of the originally filed claims recited the limitation in question.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Rejection to claims 21-23 as being unpatentable over Olsson et al. (Journal of Applied Biochemistry. 5:437-445(1983)) as applied to claim 20 above, and further in view of Tsuji et al. (Chemical Abstract 86:39099) or Friedrich et al (Biochemical Genetics, 22 (5/6): 389-394(1984)) and if necessary, further in view of Buth et al. (Biological Abstract 71059076 (1981)) is now moot in light of the cancellation of the claims.

4. Claim 20, as amended, is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsson et al. (Journal of Applied Biochemistry, 5:437-445 (1983)) for reasons of record and as follows.

Applicants amended claim 20 so as to recite "at least 20 U/L" as a threshold level in determining erythrocyte adenylate kinase activity in a sample whereby the presence of such amount is indicative of erythrocyte hemolysis in a subject.

In assaying adenylate kinase activity and during optimization procedures, Olsson et al. obtained results which appear to overlap with the values obtained by the applicants in the instant invention. Furthermore, one of ordinary skill in the art would have had reasonable expectation of success in determining a minimal threshold level to allow for minimal false positives and false negatives because experimentations pursuant to the optimization and standardization of procedures, such as precision studies and determination of threshold levels as effected by minimum capacity and maximum capacity of assays, are well-known and conventional to skilled artisans. It would have been prima facie obvious, therefore, to one of ordinary skill in the art at the time of the invention to determine the threshold level for adenylate kinase activity based on hemolysis, the actual level of which would have been a matter of routine design.

Remarks

5. While the present invention is drawn to determining adenylate kinase activity as effected by in vivo or in situ hemolysis in patients due to physiologic or pathologic causes, Olsson's study is drawn to detecting adenylate kinase activity in stored blood cells as effected by leakage of adenylate kinase from aging of erythrocytes. A person with ordinary skill in the art at the time would have appreciated the correlation between hemolysis and erythrocyte adenylate kinase

suggested by Olsson et al. as emphasized by the parallel between hemoglobin (a known indicator of hemolysis) and erythrocyte adenylate kinase taught by Olsson et al. Indeed, Olsson teaches determination of erythrocytic adenylate kinase as a measure of enzymatic activity and further teaches the critical correlation between erythrocyte adenylate kinase and hemolysis regardless of the fact that the phenomenon of hemolysis occurred in vivo or in vitro. The criticality in both methods is in the measuring of enzyme activity in adenylate kinase as it correlates to hemolysis, i.e. occurrence of "free" hemoglobin outside of an erythrocytic cell; not whether such occurrence takes place in situ or in vitro. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Olsson et al. in determining erythrocyte adenylate kinase activity in serum rather than plasma because serum and plasma are conventional alternative sample types used in clinical analysis, differing only in the presence or absence of anticoagulation.

The amendment has been considered but fails to place the application in condition for allowance.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R, Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays at 7:00 to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

11/3/99

Gailene R. Gabel
Patent Examiner
Art Unit 1641

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641